REMARKS

I. AMENDMENT TO THE CLAIMS

Claims 28-31 have been canceled solely to promote the allowance of the case and without acquiescing to the Examiner's rejections. Claims 32-37 have been rewritten as independent claims.

Claim 38 has been amended to correct its dependency.

New claims 43-48 recite the compounds of claims 32-37 and a second active agent being a dopamine agonist and its exemplary species, a monoamine oxidase inhibitor and its exemplary species, a catechol-O-methyltransferase inhibitor and its exemplary species, an acetylcholinesterase inhibitor and its exemplary species, an anti-inflammatory agent and its exemplary species, and an antiemetic and its exemplary species, accordingly. Support for new claims 43-48 is found, for example, on page 53, line 18 through page 54, line 23.

New claims 49-54 recite the compounds of claims 32-37 that are substantially free of their S isomers. Support for new claims 49-54 is found, for example, on page 43, line 22 and page 44, line 20.

Accordingly, these amendments do not constitute new matter. Entry thereof is respectfully requested.

II. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claim 32 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner states that the limitation "Cl' in the formula lacks sufficient antecedent basis in claim 28 from which it depends (Office Action, page 2). Claim 28 has been canceled and claim 32 is rewritten as independent claim. Therefore, the rejection is moot and should be withdrawn.

III. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 29 and 30 are rejected under 35 U.S.C. § 112, first paragraph, for scope of enablement, because the specification, while being enabling for the particular compounds or agents for "second active ingredient" disclosed in the specification, does not reasonably provide enablement for any compounds in general having functional properties recited in the claims herein. In particular, the Examiner states that the recitations "a dopamine agonist", "a

monoamine oxidase inhibitor", "a catechol-O-methyltransferase inhibitor", "an acetylcholinesterase inhibitor", "an antiemetic" and "an anti-inflammatory agent" are seem to be merely functional language (Office Action, page 3).

Applicants have cancelled claims 29 and 30. Therefore, the rejection is moot and should be withdrawn.

Applicants have added new claims 43-48. These claims recite the compounds of claims 32-37 and a second active ingredient being a dopamine agonist and the exemplary species (claim 43); a monoamine oxidase inhibitor and the exemplary species (claim 44); a catechol-O-methyltransferase inhibitor and the exemplary species (claim 45), an acetylcholinesterase inhibitor species and the exemplary species (claim 46); an antiemetic and the exemplary species (claim 47); and an anti-inflammatory agent and the exemplary species (claim 48). The exemplary species of the second active ingredient(s) are disclosed in the specification on page 53, line 18 through page 54, line 23. Therefore, they are fully supported by the instant specification (as admitted by the Examiner (Office Action, page 2, last paragraph)). Accordingly, new claims 43 to 48 are enabled by the disclosure.

Further, the Examiner has rejected claims 28-31 and 38-42 under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement for making solvates of the claimed compounds (Office Action, page 8).

Claims 28-31 have been cancelled, and claim 38 has been amended to depend upon claims 32-37 Claims 32-27 and 38 do not recite the term "solvate". Claims 39-42 depend upon claim 38. Therefore, the rejection is moot and should be withdrawn.

IV. REJECTION UNDER 35 U.S.C. §103 OVER HARIRI

Claims 28 and 31-42 are rejected under 35 U.S.C. § 103 as being unpatentable over Hariri et al. (WO 2003/087333, hereinafter "Hariri"). The Examiner alleges that it would have been obvious to a person skilled in the art to use the recited compounds for the treatment of Parkinson's disease because Hariri teaches that the compounds therein which encompass instant compounds, are useful for modulating the differentiation of stem or progenitor cell population, and can be employed for treating diseases which include Parkinson's disease (Office Action, page 11). Applicants respectfully traverse this rejection.

Claims 28 and 31 have been cancelled rendering the rejection moot with respect to these claims. Applicants respectfully submit that the instant application is assigned to Celgene Corporation. The claimed invention and Hariri were commonly owned at the time

the claimed invention was made by virtue of assignments. The common ownership is sufficient to disqualify Hariri as prior art in the § 103(a) rejection. See, *e.g.*, 35 U.S.C. § 103(c) and MPEP § 706.02(l)(1) and § 706.02(l)(2). Accordingly, Hariri is not prior art, for this reason alone the rejection under 35 U.S.C. § 103(a) over Hariri should be withdrawn.

Further, Applicants respectfully submit that the rejection of the pending claims over Hariri *et al.* must be withdrawn for the following reasons.

The instant claims are focused on the non-obvious use of the individual compounds recited in claims 32 to 37 to treat Parkinson's disease. These compounds are not taught or suggested by Hariri, much less their uses for the treatment of Parkinson's disease (as admitted by the Examiner, Office action, page 11, 3rd full paragraph).

In the post *KSR* Federal Circuit's decision in *Takeda*, which provides an insight as to the current legal standard concerning the (un)obviousness of chemical compounds (*Takeda*, 429 F.3d 1350 at 1360 (citing *In re Dillon*, 919 F.2d 688 at 692), the Court held that it was not obvious to select one compound out of a prior art reference that disclosed a large amount of compounds, in part, because "[r]ather than identify predictable solutions..., the prior art disclosed a broad selection of compounds any one of which could have been selected as a lead compound for further investigation." (*Id.*). To establish a *prima facie* case of obviousness when a prior art reference discloses a genus, the Office must show "[s]ome motivation to select the claimed species or subgenus [from] the prior art." ((MPEP §2144.08) (emphasis added).

Hariri discloses the methods of modulating the differentiation of stem or progenitor cell population using a broad genus of compounds. Yet it does not provide any reason to specifically select the individual compounds recited in claims 32 to 37 to treat the specific disease, *i.e.*, Parkinson's disease. Applicants respectfully submit that the Office has not pointed to any portion in Hariri that would have provided the impetus to one of skill in the art to specifically select the claimed compounds to treat Parkinson's disease. Absent any specific teaching that would have led one of skill in the art towards the specific compounds recited in claims 32 to 37, one of skill in the art would have had no reason to specifically select these compounds. The Office has failed to demonstrate why one skilled in the art would select the recited compounds in order to arrive at the instant methods. Without demonstrating why one skilled in the art would be motivated to make this specific selection, the instant claims cannot be obvious over Hariri. *See KSR*, 82 U.S.P.Q.2d at 1395 (Examiner must "identify a reason that would have prompted a person of ordinary skill...to combine the

elements in the way the claimed new invention does."). Therefore, claims 32-42 and new claims 43-54 are not obvious over Hariri.

Nonetheless, the Examiner alleges that one of ordinary skill in the art at the time of the invention would be motivated to employ the cytokine inhibitory drugs which encompass/read on instant claimed compounds with a reasonable expectation of success of treating Parkinson's disease (Office Action, page 11, 4th paragraph to page 12, 1st paragraph). Applicants traverse.

As previously argued, Hariri does not teach or suggest the individual compounds recited in claims 32 to 37, much less their use for the treatment of Parkinson's disease. The PTO has failed to explain why a person of ordinary skill in the art would have a reasonable expectation of success in arriving at the claimed method based upon the disclosure of Hariri. Such is required to establish a *prima facie* case of obviousness. *See e.g., PharmaStem Therapeutics, Inc.*, at 1342, 1360 (Fed. Cir. 2007) ("[t]he burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had a reasonable expectation of success in doing so.") (emphasis added, internal quotations omitted). It is respectfully submitted that Hariri does not provide a reasonable expectation of success in arriving at the claimed method of treating Parkinson's disease because the reference lacks an essential element – the use of the compounds recited in claims 32 to 37 to treat Parkinson's disease, as claimed. Moreover, even assuming, *arguendo*, that the claimed compounds are taught or suggested by Hariri, which they are not, there is no evidence based on the disclosure of Hariri that the claimed compounds would successfully treat Parkinson's disease, as recited in the instant claims. Thus, Hariri does not provide the requisite expectation of success. Since a reasonable expectation of success is required for finding of obviousness, a *prima facie* obviousness cannot be established. Accordingly, the rejection under 35 U.S.C. § 103 over Hariri must be withdrawn.

V. REJECTION UNDER 35 U.S.C. §103 OVER HARIRI IN VIEW OF HUCKLE

Claims 29-30 are rejected under 35 U.S.C. § 103 as being unpatentable over Hariri et al. (WO 2003/087333) as applied to claims 28 and 31-42, in view of Huckle (US 6,297,286, hereinafter "Huckle"). In particular, the examiner alleges that one skilled in the art at the time of the invention would have been motivated to combine the selective cytokine inhibitory drug composition known to treat Parkinson's disease according to Hariri with amantadine taught by Huckle with a reasonable expectation of success of treating Parkinson's

disease because Huckle teaches that amantadine can be used to treat same (Office Action, page 12). Applicants respectfully traverses this rejection.

Claims 29 and 30 have been cancelled solely to promote the allowance of the case and without acquiescing to the Examiner's rejection. Thus, the rejection is moot and Applicants respectfully request that the rejection be withdrawn.

VI. OBVIOUSNESS TYPE DOUBLE PATENTING REJECTION

Claims 28-31 and 38-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-39 of copending application No. 10/794,877 (the '877 application). The Examiner alleges that the claims of the copending application are drawn to a method of treating Parkinson's disease using a cytokine inhibitory drug which encompasses drugs of the instant claimed formula, and that the claims of the instant application are within the scope of the claims of the copending application (Office Action, page 13). Applicants respectfully disagree..

Claims 28-31 have been cancelled rendering the rejection moot with respect to these claims. It is respectfully submitted that pending claims 38-42 depend on claims 32-37, which are not rejected. In view of the amendments, the rejection is moot and should be withdrawn.

CONCLUSION

In view of the foregoing, all the rejections of the claims should be withdrawn. Reconsideration, entry of above amendment and remarks, and allowance of the pending claims are respectfully requested. Should the Examiner not agree that all claims are allowable, a personal or telephonic interview is respectfully requested to discuss any remaining issues and to accelerate the allowance of the above-identified application.

No fee is believed due in connection with this response. However, the Commissioner is hereby authorized to charge all required fees, fees under 37 C.F.R. § 1.17 and all required extension of time fees, or credit any overpayment, to Jones Day U.S. Deposit Account No. 503013, referencing Attorney Docket No. 9516-335-999.

Respectfully submitted,

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